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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/532,682

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Hideo Kawachi

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EXAMINER

WEBB, WALTER E

ART UNIT

PAPER NUMBER

1612

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/532,682	<b>Applicant(s)</b> KAWACHI, HIDEO	
	<b>Examiner</b> WALTER E. WEBB	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2010.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1, 3-7 and 9 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1 and 3-7 is/are rejected.  
7) ☒ Claim(s) 9 is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

Applicants' arguments, filed 3/19/2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### ***Claim Rejections - 35 USC § 112--previous***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3-7 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "trace amount" in claim 1 is a relative term which renders the claim indefinite. The term "trace amount" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear how small the amount of water can be and qualify as being useful in a method of separating ergosterol from a solution in water-insoluble organic solvent. The term "such a range of amount that no phase separation occurs between the water-insoluble organic solvent" renders the claims indefinite for the same reasons. This term is defined as "a trace amount of water that can be dissolved in a water insoluble organic solvent" (see pg. 7, 1<sup>st</sup> paragraph). This definition assumes that there is only one amount that

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suffices **for each** water insoluble organic solvent. The artisan would reasonably expect a range as per the example given in the specification, i.e. "approximately 1 to 100 ppm with respect to hexane" (see *Id.*).

***Claim Rejections - 35 USC § 102--previous***

1) Claim 7 remains rejected under 35 U.S.C. 102(b) as being anticipated by Bills (US 1,775,548).

Bills teaches a method of purifying ergosterol. The purifying process demonstrated crystallized product of ergosterol, which amounted to 60% of the original crude ergosterol. (See col. 2, lines 85-97.)

2) Claim 7 remains rejected under 35 U.S.C. 102(b) as being anticipated by Knol (US 2,536,753).

Knol teaches a method of recovering and purification of sterols. (See col. 1, lines 1-3.) Ergosterol is dissolved in iso-octate; water is added yielding 90% ergosterol precipitate. (See col. 7, lines 29-37.)

***Claim Rejections - 35 USC § 103—Previous***

1) Claims 1, 3 and 6-7 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Knol (US 2,536,753) in view of Bills (*supra*).

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2) Claim 5 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Knol (*supra*) and Bills (*supra*), and in further view of Nimberger et al., (US 5,498,138).

3) Claim 4 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Knol (*supra*) and Bills (*supra*) as applied to claims 1, 3 and 6-8 above, and further in view of Watannabe et al., (US 4,447,362).

### ***Response to Amendment***

Applicant has amended claim 1 as requiring the limitation of claim 8 (now cancelled). Thus, the art rejections that did not meet the limitation of claim 8 have been withdrawn.

### ***Response to Arguments***

In regard to the 112 rejection, applicant argues that the term "trace amount" does not render the claims indefinite, and for any given solvent, it is easy for a person having ordinary skill in the art to know the amount of water that can be dissolved in "aliphatic hydrocarbons, aromatic hydrocarbons, halogenated hydrocarbons" by documents or data base. Applicant also cites references disclosing solubility of water in hexane, heptane and toluene. However, the instant claims remain indefinite since the term is relative and the specification does not provide a standard for measuring a trace amount. Also, the scope of the term, in regard to "water-insoluble organic solvents", is

so broad that the artisan would not be reasonably apprised of the metes and bounds of the invention.

In regard to the rejection of claim 7 anticipated by Knol and Bills, applicant argues that the yield of ergosterol in these references "is a completely different parameter from the 'crystallinity' in the present claim 7, which means an amount of crystal component in the aggregate by measuring water of hydration by thermogravimetric analysis." Applicant states that the yield in Knol and Bills is a parameter corresponding to the recovery rate of the present invention, and that "crystallinity" can be obtained by measuring a ratio of hydrate crystals in the aggregate, which includes hydrate crystals and amorphous component. However, it is not clear whether applicant is arguing that amorphous components are part of the percentage of crystallinity or just considered via the thermogravimetric analysis when determining the amount of hydrate crystals. If the latter is true then applicant is merely relying on a measuring tool for determining the yield of hydrate crystals, which has no patentable weight in regard to the composition. As previously stated by the examiner, thermogravimetric analysis measures crystallinity of a product, it does not produce the crystallinity. In other words, claim 7 is not a product-by-process claim. The Knol and Bills references describe method of producing ergosterol from organic solvents and describe a percentage of crystallized ergosterol precipitate, falling with the claimed range of 50% to 90%. The compositions inherently comprise an aggregate. Therefore, the amount of ergosterol determined in Knol and Bills is determined in the aggregate.

In regard to the rejection of Knol in view of Bills, applicant argues that the method of separating ergosterol in the instant invention is completely different from the method of Knol. However, applicant does not clearly indicate how the methods differ. The instant claims require a solution of ergosterol in a water insoluble organic solvent and precipitation of ergosterol by cooling crystallization. Knol meets these limitations insofar as it teaches ergosterol in iso-octane, and a cooling step in the process to generate the ergosterol precipitate.

Applicant states that Bills cannot be combined with Knol since the use of water in both processes are completely different from each other. However, Knol teaches that the zinc chloride-sterol addition product can be decomposed using water or an aqueous solution to free the sterol from zinc-chloride, but does not specify the amount of water used to perform this step. Since, Bills teaches that too much water will hold ergosterol partly in colloidal suspension and too little water will cause incomplete precipitation, it would have been obvious to ensure that an effective amount of water was used in the process of Knol. It appears that it is within the purview of the artisan to use an amount of water such that two phases are not formed between the water-insoluble organic solvent and water, since adding too much water would hold ergosterol partly in colloidal suspension.

In regard to claim 5, the artisan would have been motivated to use the device of Nimberger in combination with Knol and Bills, since Bills teaches that a correct amount of water is important for precipitation. Claim 5 reads on supplying water through a fluid regulator, which monitors the amount of water administered and Numberger teaches a

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fluid regulation device. It would have been obvious to use the fluid regulator to control that the right amount of water for the precipitation of ergosterol from the organic solution of Knol. Such a device would be useful in an apparatus for mass production of ergosterol.

In regard to claim 4, applicant argues that it is not obvious to a person having ordinary skill in the art to select a solvent suitable for extracting coenzyme Q as a proper solvent for precipitating ergosterol. However, the examiner does not take the position that solvents used for precipitating coenzyme Q are useful for precipitating ergosterol. Rather, it is the examiners position that the artisan would have reasonably expected that a known solvent would have been replaced with its art recognized equivalent. Since, Watannabe teaches that hexane and isooctane are equivalent water insoluble organic solvents for extraction purposes, it would have been obvious to replace the isooctane of Knol with hexane.

***Claim Objections—Allowable Subject Matter--Previous***

Claim 9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 8:00am-4:00pm Mon-Fri EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Walter E. Webb  
/Walter E Webb/  
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612